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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0364]

Third Annual Stakeholder Meeting on the Medical Device User Fee and Modernization Act of 2002; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Third Annual Stakeholder Meeting on the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). On October 1, 2007, the user fee provisions of MDUFMA will expire. In preparation for discussions regarding legislation to reauthorize and possibly modify MDUFMA user fees, the agency is holding this public meeting to obtain stakeholder input and recommendations on various issues related to this future legislation.

DATES: The public meeting will be held on November 17, 2005, from 9 a.m. to 5 p.m. However, depending upon the level of public participation, the meeting may end early. Registration is required by October 28, 2005. All individuals wishing to make a presentation or to speak on an issue should indicate their intent and the topic to be addressed and provide an abstract of the topic to be presented by October 28, 2005.

ADDRESSES: The public meeting will be held at the Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Submit written requests to make an oral presentation to Cindy Garris (see **FOR FURTHER INFORMATION CONTACT**). Include your name, title, firm name,

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address, telephone, and fax number with your request. All requests and presentation materials should include the docket number found in brackets in the heading of this document. Submit all requests for suggestions and recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cindy Garris, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 121, FAX: 301–443–8818, e-mail: *cxg@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act (the act) to include several new significant provisions. In addition to authorizing user fees for the review of certain premarket applications, MDUFMA authorizes the following provisions: (1) Establishment of performance goals (cycle and decision) for premarket approval applications (PMAs), biologics license applications, and premarket notifications (510(k)), (2) authorization of good manufacturing practice (GMP) inspections by FDA-accredited persons (third-parties), and (3) establishment of new requirements for reprocessed single-use devices. In a letter that accompanied the user fee legislation, the agency also committed to developing performance goals for modular PMAs, maintaining performance in those programs without MDUFMA performance goals, and improving the timeliness of inspections conducted under the GMP and Bioresearch Monitoring (BIMO) programs.

MDUFMA has been amended twice since its enactment. The Medical Devices Technical Corrections Act (Public Law 108-214) (April 1, 2004),

clarified Congress's intent in areas where MDUFMA was unclear, and improved and expanded some features of MDUFMA. The Medical Device User Fee Stabilization Act of 2005 (Public Law 109-43) (August 1, 2005) provides a new fee structure and a new definition of "small business" for FY 2006 and FY 2007; it also limits section 301 of MDUFMA (section 502(u) of the act (21 U.S.C. 352(u)) to reprocessed single-use devices.

Since its passage in October 2002, the agency has been working to implement MDUFMA. An important part of this process has been the annual stakeholder meetings. Each year, FDA has held public meetings to afford interested persons the opportunity to share information and views on the implementation of MDUFMA.

On October 1, 2007, the user fee provisions of MDUFMA will expire. In order to help the agency and all stakeholders to evaluate the program and prepare for possible new legislation to reauthorize MDUFMA, FDA would like to hear from interested parties about those aspects of MDUFMA that worked well and those areas for which change should be considered. Specifically, FDA is looking for input and recommendations that may help to improve the device review program. FDA is holding this public meeting to gather such information from its stakeholders.

For additional information on MDUFMA, please see the document entitled "Background on MDUFMA" at *http://www.fda.gov/cdrh/mdufma/whitepaper.html.*

II. Agenda

On November 17, 2005, FDA is providing the opportunity for interested persons to share their views on the following topics:

- User Fee Structure—During this session, the agency will seek comments on possible user fee structures for MDUFMA II that will provide for an adequate and stable revenue base and predictable user fees.

- Premarket Review Performance Goals—During this session, interested persons may discuss the current performance goals and make recommendations for additional or alternative goals that would help to provide for timely and predictable reviews.

- Qualitative Performance Goals (e.g., Modular PMA, GMP, and BIMO Inspection Programs)—During this session, stakeholders may comment on the current qualitative performance goals and make recommendations for agency consideration of new initiatives of importance to stakeholders.

- Third-Party Inspection Program—During this session, FDA will seek recommendations for improving the participation of eligible manufacturers in the inspection program.

- Reprocessing of Single-Use Devices (SUDs)—During this session, interested stakeholders may comment on current requirements for reprocessing SUDs and make recommendations for ways the agency can provide for the continuing assurance of safe and effective reprocessed SUDs.

- Other Provisions—At the conclusion of the meeting, there will be an opportunity for a general discussion from the floor.

As stated previously, although the meeting is scheduled for a full day, depending upon the level of public participation, the meeting may end early.

III. Registration

Online registration for the meeting is required by October 28, 2005. Acceptance will be on a first-come, first-served basis. There will be no onsite registration. Please register online at *http://www.fda.gov/cdrh/meetings/120303.html*. FDA is pleased to provide the opportunity for interested persons

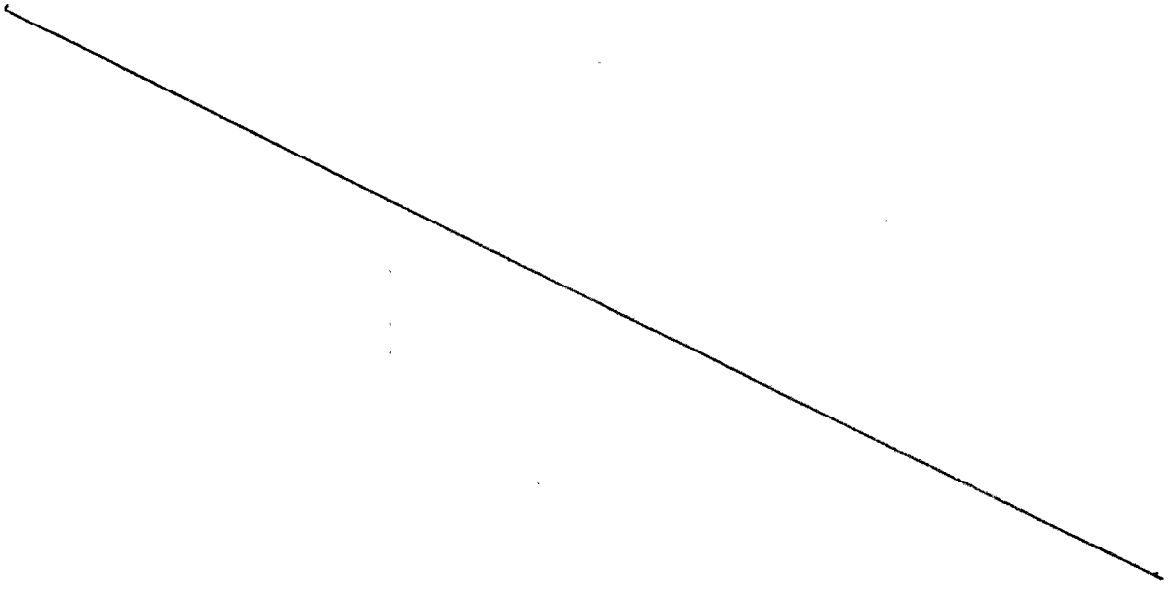
to listen from a remote location to the live proceedings of the meeting. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/120303.html* by October 28, 2005. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301–443–6597, ext. 121 by October 28, 2005.

If you need special accommodations due to a disability, please contact Cindy Garris at least 7 days in advance of the meeting.

IV. Request for Input and Materials

FDA is also interested in receiving input from stakeholders on other issues related to future user fee legislation. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**).

FDA will place an additional copy of any material it receives on the docket for this document (2005N–0364). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).



V. Transcripts

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: 9/22/05
September 22, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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